

REMARKS/ARGUMENTS

Claims 1, 3, 4, 6-12, 17-19, 31 and 32 are currently under examination and have been rejected. Applicants respectfully request reconsideration and allowance of these claims in view of the following arguments.

Claims 1, 3, 4, 6-12, 17-19, 31 and 32 stand rejected under 35 U.S.C § 103(a) as being unpatentable over WO 93/19115 in view of Lihme et al. (US 5,866,006) (Lihme). Applicants respectfully disagree.

To establish a prima facie case of obviousness the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) M.P.E.P. §2143.

The obviousness rejections should be reconsidered because there is no proper teaching for the combination of the cited references. "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight based obviousness analysis is a rigorous application of the requirement for a showing of the teaching or motivation to combine the prior art references." *In re Dembiczaik*, 50 USPQ2d 1614,

1617 (Fed. Cir. 1999)(internal citations omitted). “The showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence’.” The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In applying this law to the present claims, a finding of obvious should be reconsidered.

No clear and particular teaching to combine exists

The law requires a clear and particular teaching to be found in the cited references. Such a teaching must come from the references. In addition, broad conclusory statements are deemed not sufficient. However such broad conclusory statements are all that are proffered in the present Office action.

The present Office action in Section 3 notes: “Lihme discloses the use of conglomerating agents in combination with polysaccharide in chromatographic procedures for binding, entrapping or carrying the polysaccharide.” “Lihme discloses agarose as a conglomerating agent”. “Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to employ a conglomerating agent as the secondary component of the porous material in WO'115 motivated by the desire to bind, entrap or carry the polysaccharides, which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification."

The logic of this statement is not in accord with the cited rule. The Office action notes that Lihme uses a conglomerating agent in combination with polysaccharide in chromatographic procedures for binding, entrapping or carrying the polysaccharide. The Office action proposes that alone is suggested as motivation to combine with other references. However, the mere fact that a reference includes some of the elements of an examined claim plainly is not sufficient to form a clear and particular motivation to combine references. Were this true every reference that includes elements of a claim would then per se also teach combination with every other reference teaching other elements within a claim. Nothing, either from the prior art, or in knowledge generally available to one of ordinary skill in the art has been cited as a clear and specific teaching for the combination of two dissimilar references.

The text from Lihme teaches away from the cited combination. Lihme teaches fluidized bed chromatography, while WO'115 and the instant application teach packed bed chromatography. Applicants submit that Lihme relates specifically to fluidized bed

chromatography, where there is no need for the beads to have the rigidity and flow properties WO '115 describes, because unlike in a packed bed where pressure drop appears when a liquid passes across a packed bed, in fluidized bed chromatography the beads float on the liquid. The conglomerates made by Lihme avoid uncontrolled sedimentation or flotation, which are not problems in a packed bed.

The Proposed Combination Renders WO'115 Unfit for its Intended Purpose

The law also states that a combination is not permissible if the combination of elements from one source would render the technology from the other cited source unfit for its intended purpose.

The intended purpose of WO'115 is to provide high performance polysaccharide gels with improved mechanical stability and reduced pressure drop. This was achieved by introducing super-pores (page 3, second paragraph). Thus, prior to the teaching of the instant application, adding a secondary component to within the super-pores of WO '115, clearly would contradict the purpose of the WO '115 invention. There is no motive for a person skilled in the art to fill pores of WO'115, when the super-pores are the unique features of the invention of WO'115. Given these facts, the cited combination is not proper.

The Instant Invention Provides Unexpected Results

Applicants also submit that the instant application provides quite unexpected result when compared to WO '115. With the presence of secondary component in both the super-pores and the gel phase of the main component, a superior separation is achieved now by the inventors, which could not be achieved with just super-porous agarose beads, see p. 8 of the instant application, under "Functional testing...".

In view of the foregoing, Applicants respectfully submit the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 1, 3, 4, 6-12 and 31 under 35 U.S.C. § 103(a) as, "being unpatentable over WO 93/19115 in view of Schaeffer et al (US 4,111,838)." Applicants respectfully disagree.

The present Office action in Section 3 notes: "Schaeffer discloses a chromatographic material comprising an inorganic support-polysaccharide particulate matrix. The matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to polysaccharide particles (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as the secondary component of the porous material in WO'115 motivated by the desire to bind, or carry the polysaccharides,

which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification."

Applicants respectfully disagree. Applicants submit that no clear and particular teaching to combine exists. Applicants first submit that the logic of this statement is not in accord with the cited rule. The Office action notes that Schaeffer disclosed a matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to polysaccharide particles. The Office action proposes that alone is suggested as motivation to combine with other references. However, the mere fact that a reference includes some of the elements of an examined claim plainly is not sufficient to form a clear and particular motivation to combine references. Were this true every reference that includes elements of a claim would then per se also teach combination with every other reference teaching other elements within a claim. Nothing, either from the prior art, or in knowledge generally available to one of ordinary skill in the art has been cited as a clear and specific teaching for the combination of two dissimilar references.

Applicants submit that the Examiner erred in the interpretation of Schaeffer as well. Applicants submit that Schaeffer disclose a matrix comprising an inorganic support with insoluble polysaccharide particles attached thereto. Applicants wish to emphasize that in Schaeffer, it is polysaccharide particles that are covalently attached to an inorganic support. Applicants submit that if you simply replaced the Sepharose beads used in the

example with superporous agarose according to WO '115, you would not end up with a product where the inorganic material is in the super-pores. See Schaeffer col. 1, lines 56-61: Polysaccharide particles (plurals) attached to inorganic support. In the presently claimed invention, the secondary component is present both in super-pores and the gel phase (where pores are much smaller) of the polysaccharides.

Applicants also submit that the text from Schaeffer teaches away from the cited combination. Schaeffer teaches a composition of matrix with an inorganic support, attached thereon with insoluble particles of polysaccharides (abstract), while WO'115 and the instant application teach a composition of polysaccharides with secondary components both in the super-pores and in the gel phase. Applicants submit that it is inconceivable for the inorganic support of Schaeffer to be present in the super-pores of the current claimed invention.

The law also states that a combination is not permissible if the combination of elements from one source would render the technology from the other cited source unfit for its intended purpose.

The intended purpose of WO'115 is to provide high performance polysaccharide gels with improved mechanical stability and reduced pressure drop. This was achieved by introducing super-pores (page 3, second paragraph). Thus, prior to the teaching of the

instant application, adding a secondary component to within the super-pores of WO '115, clearly would contradict the purpose of the WO '115 invention. There is no motive for a person skilled in the art to fill pores of WO'115, when the super-pores are the unique features of the invention of WO'115. Given these facts, the cited combination is not proper.

Applicants also submit that the instant application provides quite unexpected result when compared to WO '115. With the presence of secondary component in both the super-pores and the gel phase of the main component, a superior separation is achieved now by the inventors, which could not be achieved with just super-porous agarose beads, see p. 8 of the instant application, under "Functional testing...".

In view of the foregoing, Applicants respectfully submit the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 1, 3, 4, 6–12, 18 and 31 under 35 U.S.C. § 103(a) as, "being unpatentable over WO 93/19115 in view of Manganaro et al (US 5,155,144)." Applicants respectfully disagree.

The Examiner states, "Manganaro discloses that the microporous sheet for use in chromatography apparatus comprises a polymeric matrix including polyvinyl chloride

beads and active polysaccharides (abstract, column 2, lines 65-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ polyvinyl chloride beads as the secondary component of the porous material in WO'115 motivated by the desire to bind the active polysaccharides, which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification.”

Applicants respectfully disagree. Applicants submit that no clear and particular teaching to combine exists. Applicants first submit that the logic of this statement is not in accord with the cited rule. The Office action notes that Manganaro discloses that the microporous sheet for use in chromatography apparatus comprises a polymeric matrix including polyvinyl chloride beads and active polysaccharides. The Office action proposes that alone is suggested as motivation to combine with other references. However, the mere fact that a reference includes some of the elements of an examined claim plainly is not sufficient to form a clear and particular motivation to combine references. Were this true every reference that includes elements of a claim would then per se also teach combination with every other reference teaching other elements within a claim. Nothing, either from the prior art, or in knowledge generally available to one of ordinary skill in the art has been cited as a clear and specific teaching for the combination of two dissimilar references.

Applicants submit that the Examiner erred in the interpretation of Manganaro as well. Applicants submit that Manganaro disclose a porous sheet comprises a polymeric resinous matrix (polyvinyl chloride) with an organic matrix (polysaccharide) dispersed therein (column 2, line 51-55). Applicants wish to emphasize that in Manganaro, it is polysaccharide particles that are dispersed in the matrix. Applicants submit that if you simply replaced the organic medium (polysaccharide) of Manganaro with superporous agarose according to WO '115, you would not end up with a product where polyvinyl chloride is in the super-pores. In the presently claimed invention, the secondary component is present both in super-pores and the gel phase (where pores are much smaller) of the polysaccharides.

Applicants also submit that the text from Manganaro teaches away from the cited combination. Manganaro teaches a composition of a porous sheet comprised of polymeric resinous matrix (polyvinyl chloride) having dispersed therein an organic medium (polysaccharide), while WO'115 and the instant application teach a composition of polysaccharides with secondary components both in the super-pores and in the gel phase. Applicants submit that it is inconceivable for the polyvinyl chloride of Manganaro to be present in the super-pores of the current claimed invention.

The law also states that a combination is not permissible if the combination of elements from one source would render the technology from the other cited source unfit for its intended purpose.

The intended purpose of WO'115 is to provide high performance polysaccharide gels with improved mechanical stability and reduced pressure drop. This was achieved by introducing super-pores (page 3, second paragraph). Thus, prior to the teaching of the instant application, adding a secondary component to within the super-pores of WO '115, clearly would contradict the purpose of the WO '115 invention. There is no motive for a person skilled in the art to fill pores of WO'115, when the super-pores are the unique features of the invention of WO'115. Given these facts, the cited combination is not proper.

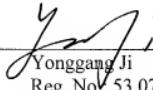
Applicants also submit that the instant application provides quite unexpected result when compared to WO '115. With the presence of secondary component in both the super-pores and the gel phase of the main component, a superior separation is achieved now by the inventors, which could not be achieved with just super-porous agarose beads, see p. 8 of the instant application, under "Functional testing...".

In view of the foregoing, Applicants respectfully submit the Examiner's rejections cannot be sustained and should be withdrawn.

In view of the foregoing, Applicants respectfully assert the Examiner's rejection can not be sustained and should be withdrawn. Applicants believe that claims 1, 3, 4, 6-12, 17-19, 31 and 32, are in allowable form and earnestly solicit their allowance.

Respectfully submitted,

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